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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,293	09/14/2000	Catherine A. McCall	AL-2-C4	9793

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/662,293	MCCALL ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/13/03; 7/21/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-51* is/are pending in the application.

4a) Of the above claim(s) *40-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/21/03; 12/18/00*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 25-51 are pending.

2. Applicant's election with traverse of Group I, Claims 9-12, 14-17 and 19 (now claims 25-39) drawn to an isolated protein from Dermatophagoides farinae, filed 8/13/03, is acknowledged. The traversal is on the grounds that the method of identifying in Group III (claims 40-45) and the method of treating in group V (claims 46-51) require the use of the proteins claimed by the claims of Group I. The claims of Group III and V do not expand the scope of the claim coverage of Group I. This is not found persuasive because of the reasons set forth in the restriction mailed 7/2/03. Inventions of Groups III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of identifying (claims 40-45) versus the method of treating (claims 46-51) differs with respect to their method steps and endpoint. Inventions of Group I and Groups (III and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in materially different process such as binding assays, identifying compound and making antibody. Therefore, they are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore, the requirement of Group I (now claims 25-39) and Groups II-VI is still deemed proper and is therefore made FINAL.

3. Claims 40-51 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 25-39 are being acted upon in this Office Action.

5. Claim 33 is objected to because it depends from canceled claim 1.

6. Applicant should amend the first line of the specification to update the relationship between the instant application and 09/292,225, filed 4/15/099, which is now Pat No. 6,455,686.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 25-28, and 30-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) an isolated protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21, (2) an isolated protein fragment consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 13, (3) an isolated protein encoded by a nucleic acid molecule comprising SEQ ID NO: 16, SEQ ID NO: 19, SEQ ID NO: 22, SEQ ID NO: 14, SEQ ID NO: 17, and SEQ ID NO: 20, (4) a composition or kit comprising the isolated protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21, (5) a composition or kit comprising the isolated protein fragment consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 13, and (6) a composition or kit comprising the isolated protein encoded by a nucleic acid molecule comprising SEQ ID NO: 16, SEQ ID NO: 19, SEQ ID NO: 22, SEQ ID NO: 14, SEQ ID NO: 17, and SEQ ID NO: 20 for identifying an animal susceptible to an allergic response to mite, **does not** reasonably provide enablement for *any* isolated protein as set forth in claims 25-28, and 30-34 and any therapeutic composition comprising said protein for treating an allergic response to a mite as set forth in claims 35-39. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a house dust mite chitinase from Der HMW-map protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21; the said isolated protein is encoded by a nucleic acid molecule comprising SEQ ID NO: 16, SEQ ID NO: 19, SEQ ID NO: 22, SEQ ID NO: 14, SEQ ID NO: 17, and SEQ ID NO: 20. The specification further discloses isolated protein fragment consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 13 as well as composition and kit comprising the isolated protein or fragment mentioned above for identifying an animal susceptible to an allergic response to mite.

The specification does not teach how to make *any* isolated protein as set forth in claims 25-28, and 30-34 for a therapeutic composition for treating an allergic response to a mite (claims 35-39) for the following reasons.

As to claim 25 (a), there is insufficient guidance as to the structure associated with function, without the nucleotide sequence of all protein encoded by any nucleic molecule that is at least about 150 nucleotides that hybridize to which 150 nucleotides of a nucleic acid sequence selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22. Further, the term "comprising" is open-ended. It expands the undisclosed nucleic acid that is at least about 150 nucleotides to include additional nucleotides at either or both ends. There is a lack of guidance as to which nucleotides to be added and whether the resulting nucleotide encodes the same protein and maintains the same function as the nucleic acid set forth in SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22. Further, there is insufficient in vivo working example demonstrating the claimed therapeutic composition (claims 35-39) could treat an allergic response to mite.

The state of the prior art as exemplified by Wallace *et al* is such that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable. Even if the probe is a 20mer, the total number of hits in a database search was 143,797,728, there is no guarantee that polynucleotide encodes the same protein. Given the indefinite number of protein encoded by the undisclosed nucleic acid molecule, there is insufficient working example demonstrating that all undisclosed protein is effective for treating allergy to mite.

As to claim 25 (b), there is insufficient guidance as to the structure and function of all protein encode by any nucleic acid fragment since it merely require at least about 15 nucleotides, which is about 5 amino acids. The rest of the polynucleotide encoding the isolated protein is not enabled, let alone encoding the a protein that has the same function as the protein encoded by a nucleic acid of SEQ ID NO: 16, SEQ ID NO: 19 or SEQ ID NO: 22. Further, the term "comprising" is open-ended. It expands the fragment to include additional nucleotides at either or both ends so long the nucleotide is at least about 15 nucleotides that hybridize to SEQ ID NO: 16, SEQ ID NO: 19 or SEQ ID NO: 22. There is insufficient in vivo working example demonstrating that all undisclosed protein is effective for treating allergic response to mite. Given the indefinite number of protein, it is unpredictable which undisclosed protein has the same structure and function as SEQ ID NO: 16, SEQ ID NO: 19 or SEQ ID NO: 22, in turn, effective for treating allergic response to mite.

As to claim 26, there is insufficient guidance as to the structure and function of any protein encoded by any nucleic acid molecule having a nucleic acid sequence at least 95% identity to the nucleic acid sequence of SEQ ID NO: 14 because a 95% identity is at least 5% difference, which is equivalent to at least 27 nucleotides different from SEQ ID NO: 14. There is insufficient guidance as to which amino acids within the full-length polypeptide encoded by SEQ ID NO: 14, the corresponding nucleotides to be added, deleted or added and whether the resulting protein maintains the same structure and function as the protein encoded by SEQ ID NO: 14. The same reasons apply to any nucleic acid molecule having a nucleic acid sequence at least 95% identity to the nucleic acid sequence of SEQ ID NO: 17 and SEQ ID NO: 20.

Skolnick *et al* teach that sequence-based methods for function prediction are inadequate and knowing a protein's structure does not tell one its function (See abstract, in particular).

It is known in the art that the relationship between the amino acid sequence of a protein (polypeptide) and its tertiary structure (i.e. its binding activity) are not well understood and are

not predictable (see Ngo et al., in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz, et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495). There is no recognition in the art that sequence with identity predicts biological function. It is known in the art that even single amino acid changes or differences in a protein's amino acid sequence can have dramatic effects on the protein's function.

Fasler *et al* teach that peptides derived from house dust mite Der p1 are modified by single amino acid substitutions at positions 173, 175, 176, 180 and 181 with alanine or glycine failed to induce Der p1 specific T cell proliferation and IL-2, IL-4 and IFN-γ production. Fasler *et al.* further teach that substituting a neutral amino acid residue such as Asn at position 173 with either a basic Lysine, which is a hydrophobic amino acid residue did not induce T cell proliferation and cytokine production. However, substitution amino acid positions other than 173, 175, 176, 180 and 181 induces normal or only slightly reduced proliferative responses and cytokine production by T cells (page 524, in particular). Without the amino acid sequence, it is unpredictable which undisclosed protein has the same function, let alone for a pharmaceutical composition for treating allergic response to mite without any in vivo working example.

As to claim 27 (a), there is insufficient guidance as to the structure and function of any protein comprising which 30 contiguous amino acid identical to SEQ ID NO: 15, SEQ ID NO: 18 or SEQ ID NO: 21. So long the protein has 30 contiguous amino acid sequence from SEQ ID NO: 15, SEQ ID NO: 18 or SEQ ID NO: 21, the term "comprising" is open-ended. It expands the fragment to include additional amino acids at either or both ends. There is insufficient guidance for the rest of the amino acid sequence of the undisclosed protein without the amino acid sequence, much less having the same function as a protein having an amino acid sequence comprising SEQ ID NO: 15, SEQ ID NO: 18 or SEQ ID NO: 21. Further, there is insufficient in vivo working example demonstrating that the undisclosed protein could treat all disease such as allergic response to mite.

As to claim 27 (b), there is insufficient guidance as to the structure and function of any protein comprising an amino acid sequence at least 90% identical to the full-length polypeptide of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21 because sequence-based methods for function prediction are inadequate and knowing a protein's structure does not tell one its function as taught by Skonick et al (See abstract, in particular). A 90% identity means a 10% difference. There is a lack of guidance as to which amino acids within the full-length polypeptide of SEQ ID NO: 15, SEQ ID NO: 18 or SEQ ID NO: 21 can be change such as substitution, deletion, or

addition and whether the modified polypeptides maintain the same structure and function as the full-length polypeptide of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21. Further, the term comprising is open ended. It expands the protein fragments of SEQ ID NO: 5, 6, 7, 10, 11, and 13 (claims 27(b), and claim 30) to include additional amino acids at either or both ends. There is a lack of guidance as to which undisclosed amino acids to be added and whether the modified polypeptides maintain the same structure and function as the full-length polypeptide of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21, let alone for treating all disease such as allergic response to mite.

With regard to claims 28, 31, and 32, in addition to the problems in claim 25 mentioned above, there is inadequate guidance and working example of which *immune response* against the undisclosed protein *when* administered to an animal, which epitope within full-length of the undisclosed protein is resistant to β-elimination, which epitope within full-length of the undisclosed protein is resistant to proteinase –K digestion, which epitope within full-length of the undisclosed protein reacts to which test for glycosylated proteins, or binds to dog IgE from dogs allergic to mite or feline IgE from cat allergic to mites. Without the amino acid sequence, any kit (claims 33-34), and pharmaceutical composition (claims 35-37 and 39) comprising said undisclosed proteins are not enabled. Even if the pharmaceutical composition is limited to the specific protein as set forth in claim 38, there is a lack of in vivo working example demonstrating that the claimed protein could treat an allergic response to all mites.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

9. Claims 25-28, 30-37 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* isolated protein as set forth in claims 25-28, and 30-34 and any therapeutic composition comprising said protein for treating an allergic response to a mite as set forth in claims 35-39.

The specification discloses only a house dust mite chitinase from Der HMW-map protein comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21; the said isolated protein is encoded by a nucleic acid molecule comprising SEQ ID NO: 16, SEQ ID NO: 19, SEQ ID NO: 22, SEQ ID NO: 14, SEQ ID NO: 17, and SEQ ID NO: 20. The specification further discloses isolated protein fragment consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 13 as well as composition and kit comprising the isolated protein or fragment mentioned above for identifying an animal susceptible to an allergic response to mite.

With the exception of the specific isolated protein mentioned above for identifying an animal susceptible to an allergic response to mite, there is inadequate written description about the structure associated with function of all isolated protein encoding by any nucleic acid molecule comprising which 150 nucleotides that hybridize in a soluble to a nucleic acid sequence selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22 (claim 25(a)). Further, the term "comprising" is open-ended. It expands the undisclosed nucleic acid to include additional nucleotides at either or both ends. There is inadequate written description about which nucleotides to be added and whether the resulting nucleotide encodes the same protein and maintains the same function set forth in SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22.

As to claim 25 (b), there is insufficient guidance as to the structure and function of all protein encode by any nucleic acid fragment since it merely require at least about 15 nucleotides that hybridizes to nucleic acid molecule of SEQ ID NO: 16, SEQ ID NO: 19 or SEQ ID NO: 22. Further, the term "comprising" is open-ended. It expands the fragment to include additional nucleotides at either or both ends so long the nucleotide is at least about 15 nucleotides that

hybridize to SEQ ID NO: 16, SEQ ID NO: 19 or SEQ ID NO: 22. The rest of the polynucleotide encoding the isolated protein is not adequately described without the nucleotide sequence.

As to claim 26, there is inadequate written description about the structure associated with function of any protein encoded by any nucleic acid molecule having a nucleic acid sequence at least 95% identity to the nucleic acid sequence of SEQ ID NO: 14 because a 95% identity is at least 5% difference, which is equivalent to at least 27 nucleotides different from SEQ ID NO: 14. There is inadequate written about which nucleotides and the corresponding amino acids within the full-length polypeptide encoded by SEQ ID NO: 14 to be added, deleted or added and whether the resulting protein encoded by the undisclosed nucleotide maintains the same structure and function as SEQ ID NO: 14. The same reasons apply to any nucleic acid molecule having a nucleic acid sequence at least 95% identity to the nucleic acid sequence of SEQ ID NO: 17 and SEQ ID NO: 20.

As to claim 27(a), there is inadequate written description about the structure associated with function of any protein comprising which 30 contiguous amino acid sequence identical to SEQ ID NO: 15, SEQ ID NO: 18 or SEQ ID NO: 21 without the amino acid sequence. Since the protein merely comprises any 30 contiguous amino acids from SEQ ID NO: 15, SEQ ID NO: 18 or SEQ ID NO: 21, the rest of the amino acid sequence of the undisclosed protein is not adequately described.

As to claim 27(b), there is inadequate written description about the structure associated with function of any protein comprising an amino acid sequence at least 90% identical to the full-length polypeptide of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21. A 90% identity means a 10% difference. This is equivalent to 56 amino acids different in SEQ ID NO: 15 and SEQ ID NO: 18, and 54 amino acids difference in SEQ ID NO: 21. There is a lack of written description about which amino acids within the full-length polypeptide of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21 can be change such as substitution, deletion, or addition and whether the modified polypeptides maintain the same structure and function as the full-length polypeptide of SEQ ID NO: 15, SEQ ID NO: 18 and SEQ ID NO: 21. Further, the term "comprising" is open ended. It expands the protein fragments consisting of an amino acid sequence of SEQ ID NO: 5, 6, 7, 10, 11, and 13 (claims 27(b), claim 30) to include additional amino acids at either or both ends. Thus the undisclosed fragment "comprising" the undisclosed amino acids is not adequately described.

With regard to claims 28, 31, and 32, in addition to the problems in claim 25 mentioned above, there is inadequate written description about which *immune response* against the undisclosed protein *when* administered to an animal, let alone which epitope in the undisclosed protein is resistant to β-elimination, which epitope in the undisclosed protein is resistant to proteinase –K digestion, which epitope in the undisclosed protein reacts to which test for glycosylated proteins, or binds to dog IgE from dogs allergic to mite or feline IgE from cat allergic to mites. Since any of the proteins mentioned above are adequately described, it follows that any kit (claims 33-34), and pharmaceutical composition (claims 35-37 and 39) comprising said undisclosed proteins are not adequately described.

Further, the specification discloses only Der HMW-map protein from dermatophagoides farinae. Given the lack of an additional species of Der HMW-map protein, one of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in a **patent** granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an **international application** by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 25, 31-32, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 5,866,788 (filed Sept 1995; PTO 892).

The '788 patent teaches an isolated protein such as flea chitinase encoded by a nucleic acid molecule of SEQ ID NO: 1 comprising a fragment of 36 nucleotides such as TTC GAC GGT CTA GAC CTT GAT TGG GAG TAC CCA GGA identical to the claimed nucleic acid of SEQ ID NO: 16, SEQ ID NO: 22 and SEQ ID NO: 19 wherein the reference fragment is at least 15 nucleotides in length (See Figure 1A, reference polynucleotide sequence of SEQ ID NO: 1, nucleotides 445-480, amino acid residues 138-150, in particular). The reference flea chitinase protein inherently comprises epitope that binds to IgE, epitope that resistant to β-elimination, epitope that resistant to proteinase k digestion and epitope that react to a test designed to detect glycosylated protein (See col. 13, Example 16, in particular). The '788 patent further teaches a therapeutic composition comprising the reference protein encoded by the reference nucleic acid for controlling insect pests (See abstract, in particular). A composition is a composition, irrespective of its intended use. Thus, the reference teachings anticipate the claimed invention.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 25, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 5,866,788 (filed Sept 1995; PTO 892) in view of US Pat No 6,060,590 (filed March 1998; PTO 892).

The teachings of the '788 patent have been discussed supra.

The claimed invention in claims 33 and 34 differs from the teachings of the reference only that a kit comprising the isolated protein encoded by a nucleic acid molecule comprising a fragment of any of nucleic acid sequence selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22.

The '590 patent teaches a kit comprising a chitinase related protein for detection of the reference chitinase related protein CHRP (see column 30, line 12-40, in particular). The reference kit comprises all the necessary reagents such as vials, tubes, and carriers.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the CHRP protein the kit as taught by the '590 patent for protein encoded by a nucleic acid molecule comprising a fragment of any of nucleic acid sequence selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22 as taught by the '788 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One would have been motivated, with a reasonable expectation of success to do this for convenience and commercial expedience. A kit will allow for ease of use for the practitioner since all the necessary reagents are included in a kit as taught by '590 patent (see column 30, line 12-40, in particular).

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 25-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-37, and 40-42 of copending Application No. 10/218,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because all pending claims 25-39 of USSN 09662,293 are drawn to nearly the same isolated protein. The issuance of a patent to instant application would encompass the pending claims 32-37, and 40-42 of USSN 10/218,743 for the following reasons.

(1) Claim 25 of instant USSN 09/662,293 recites an isolated protein encoded by a nucleic acid molecule selected from the group consisting of: (a) a nucleic acid molecule comprising at least about 150 nucleotides wherein said nucleic acid molecule comprising at least about 150 nucleotides hybridize in a solution comprising 1 X SSC and 0. % formamide, at a temperature of about 50°C, to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 6, SEQ ID NO: 19 and SEQ ID NO: 22; and (b) a nucleic acid molecule comprising a fragment of any or said nucleic acid molecule of (a), wherein said fragment comprises at least about 15 nucleotides, the issuance of a patent to instant application would encompass the pending claim 32 of copending application USSN 10/218,743 which recites an isolated protein encoded by a nucleic acid molecule selected from the group consisting of: (a) a first nucleic acid molecule comprising at least about 150 nucleotides wherein said nucleic acid molecule comprising at least about 150 nucleotides hybridize in a solution comprising 1 X SSC and 0. % formamide, at a temperature of about 50°C, to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 6, SEQ ID NO: 19 and SEQ ID NO: 22; and (b) a nucleic acid molecule comprising a fragment of any or said nucleic acid molecule of (a), wherein said fragment comprises at least about 15 nucleotides.

(2) Claim 28 of USSN 09/662,293 recites the isolated protein of claim 25 wherein said protein when administered to animal, elicits an immune response against a protein having the amino acid sequence of SEQ ID NO: 18, the issuance of a patent to instant application would include claim 33 of copending Application No. 10/218,743 which recites the protein of claim 32 wherein said protein, when administered to an animal, elicits an immune response against a Der

HMW-map protein because the protein having SEQ ID NO: 18 is the same Der HMW-map protein and would inherently elicits an immune response when administered to an animal.

(3) Claim 29 of USSN 09/662,293 recites the isolated protein of claim 25 wherein said protein is encoded by a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 14, SEQ ID NO: 17 and SEQ ID NO: 20, the issuance of a patent to instant application would include the same protein in claim 34(a) of copending Application No. 10/218,743.

(4) Claim 26 of USSN 09/662,293 recites the isolated protein of claim 25 wherein said protein is encoded by a nucleic acid molecule having a nucleic acid sequence at least about 95% identical with a nucleic acid sequence selected from the sequence selected from the group consisting of SEQ ID NO: 14, SEQ ID NO: 17 and SEQ ID NO: 20, the issuance of a patent to instant application would anticipate the protein encode by a nucleic acid comprising an *allelic variant* of a nucleic acid comprising any of nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 14, SEQ ID NO: 17 and SEQ ID NO: 20 in claim 34 (b) of copending Application No. 10/218,743 because a specie anticipates a genus (allelic variant).

(5) Claim 27(b) of USSN 09/662,293 recites the isolated protein of claim 25 wherein said protein is encoded by a nucleic acid molecule having a nucleic acid sequence at least about 90% identical with a nucleic acid sequence selected from the sequence selected from the group consisting of SEQ ID NO: 14, SEQ ID NO: 17 and SEQ ID NO: 20, the issuance of a patent to instant application would anticipate the protein encode by a nucleic acid comprising an *allelic variant* of a nucleic acid comprising any of nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 14, SEQ ID NO: 17 and SEQ ID NO: 20 in claim 34 (b) and claim 35(a) of copending Application No. 10/218,743 because a specie anticipates a genus (allelic variant).

(6) Claim 30 of USSN 09/662,293 recites the isolated protein of claim 25 wherein said protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 18, and SEQ ID NO: 21, the issuance of a patent to instant application would include the same protein in claim 35(a) of copending Application No. 10/218,743 because claim 35(a) recites the isolated protein of claim 32, wherein said protein is selected from the group consisting of: (a) a protein comprising an

amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 18, SEQ ID NO: 21, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 31, SEQ ID NO: 32, SEQ ID NO: 33, SEQ ID NO: 35, SEQ ID NO: 38, SEQ ID NO: 41 and SEQ ID NO:44.

(7) Claim 31 of USSN 09/662,293 recites the protein of claim 25, wherein the said protein selectively binds to IgE, which is the same as claim 36 of copending Application No. 10/218,743.

(8) Claim 32 of USSN 09/662,293 recites the protein of claim 25, wherein said protein comprises an epitope having at least one identifying characteristic selected from the group consisting of: (a) said epitope is resistant to β-elimination of peptides; (b) said epitope is resistant to protein k digestion; (c) said epitope is reactive to a test designed to detect glycosylated proteins, wherein said epitope binds to an IgE selected from the group consisting of dogs allergic to mites and feline IgE from cats allergic to mites, which is identical to claim 37 of copending Application No. 10/218,743.

(9) Claims 33 and 34 of USSN 09/662,293 recites an assay kit for testing if an animal is susceptible to or has an allergic response to mite, said kit comprising the isolated protein of claim 25 which is the same as the kit in claim 40 of copending Application No. 10/218,743.

(10) Claim 35 of USSN 09/662,293 recites a pharmaceutical composition for treating an allergic response to a mite, said therapeutic composition comprising an isolated protein encoded by a nucleic acid molecule selected from the group consisting of: (a) a nucleic acid molecule comprising at least about 150 nucleotides wherein said nucleic acid molecule comprising at least about 150 nucleotides hybridize in a solution comprising 1 X SSC and 0. % formamide, at a temperature of about 50°C, to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 6, SEQ ID NO: 19 and SEQ ID NO: 22; and (b) a nucleic acid molecule comprising a fragment of any or said nucleic acid molecule of (a), wherein said fragment comprises at least about 15 nucleotides, the issuance of a patent to instant application would include the therapeutic composition comprising the same protein in the pending claim 41 of copending application USSN 10/218,743 because pending claim 41 recites a therapeutic composition for treating an allergic response to a mite, wherein said therapeutic composition comprises the an isolated protein encoded by a nucleic acid molecule selected from the group consisting of: (a) a first nucleic acid molecule comprising at least about 150 nucleotides

wherein said nucleic acid molecule comprising at least about 150 nucleotides hybridize in a solution comprising 1 X SSC and 0. % formamide, at a temperature of about 50°C, to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22; and (b) a nucleic acid molecule comprising a fragment of any or said nucleic acid molecule of (a), wherein said fragment comprises at least about 15 nucleotides.

(11) claim 36 of USSN 09/662,293 recites the composition wherein the protein is encoded by a nucleic acid molecule having a nucleic acid sequence at least 95% identical with a nucleic acid sequence from the group consisting of SEQ ID NO: 14, SEQ ID NO: 17 and SEQ ID NO: 20. The issuance of a patent to instant application would include the composition comprising the same protein encoded by the complement nucleic acid sequence of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22 in claim 41 of copending application USSN 10/218,743.

(12) Further, the issuance of a patent to claims 37-39 of USSN 09/662,293 would include the composition comprising the same protein encoded by the complement nucleic acid sequence of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22 in claim 41 of copending application USSN 10/218,743. The term "comprising" is open-ended. It expands the protein that is at least 30 contiguous amino acid sequence identical in sequence to at least 30 amino acids sequence from SEQ ID NO: 15, SEQ ID NO: 18 or SEQ ID NO: 21 to included the protein encoded by the complement nucleic acid sequence of SEQ ID NO: 16, SEQ ID NO: 19 and SEQ ID NO: 22 in claim 41 of copending application USSN 10/218,743.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

20. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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